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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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06/14/2006

Daniela Petrova Peneva

31,692 USA

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23307

7590

04/24/2009

FOX ROTHSCHILD LLP
2000 MARKET STREET
10th Floor
PHILADELPHIA, PA 19103

EXAMINER

SMITH, CHAIM A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,747	Applicant(s) PENEVA ET AL.	
	Examiner CHAIM SMITH	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: Claim 4 is directed to the bioactive substances of natural origin of claim 2. Claim 2 however is not directed to said bioactive substance. Claim 3 however is directed to bioactive substances of natural origin and it appears claim 4 is meant to depend from claim 3. The examiner therefore has treated claim 4 as if it depends from claim 3.
2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Regarding claim 2, it is unclear as to whether the ratio is by weight, volume or a combination of weight and volume.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4 rejected under 35 U.S.C. 102(b) as being anticipated by Aleksandrov BG 104513.
6. Regarding claims 1, 3, and 4, Aleksandrov discloses a synbiotic product containing a low-lactose soured cows milk product, a low-lactose hydrolysate having greater than 95% degraded milk casein, saccharose, pectin, and dextrose wherein the milk is soured with selected strains of *Lactobacillus delbrueckii subsp. bulgaricus*, and the synbiotic product is used as a carrier of bioactive substances of natural origin including hypericum and essential oils ('513 English translation; page 6, ln 13 - page 7, ln 1, and claims 1 - 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aleksandrov BG 104513 in view of Reddy USPN 6,080,401.

10. Aleksandrov teaches the production of a 3 gram tablet which contains by weight 1.5 grams of dry sour-milk and bacterial culture, .241 grams of extracts and other ingredients, and the remainder being 1.259 grams of dextrose (page 8, ln 16 – 19).

Aleksandrov does not teach a specific ratio of dry sour milk product and bacterial culture in the synbiotic product. Reddy however teaches a synbiotic product (title; herbal and pharmaceutical drugs enhanced with probiotics) prepared from *Lactobacillus bulgaricus*, dry milk product, and dextrose (col. 9, ln 58 – col. 12, ln 48). Reddy further teaches that the amount of dry milk and bacterial culture (probiotics) would be varied according to the concentration of bacteria present in a particular preparation and that even minimal amounts had a significant effect in enhancing the therapeutic effect of the herbs (col. 27, ln 35 - 42). It therefore would have been obvious to one of ordinary skill in the art at the time of the invention to have optimized the ratios of the synbiotic in the product of Aleksandrov as suggested by Reddy. One of ordinary skill in the art would have been motivated to do so in order to enhance the efficacy of an administered herbal extract. Further the discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). In developing a synbiotic product, properties such as probiotic amounts and bacterial concentrations are important. It appears that the precise ingredients as well as their proportions affect the therapeutic effects of the herbal extracts of the product, and

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thus are result effective variables which one of ordinary skill in the art would routinely optimize.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHAIM SMITH whose telephone number is (571)270-7369. The examiner can normally be reached on Monday-Thursday 7:30-5:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. S./

Chaim Smith

Examiner, Art Unit 1794

16 April 2009

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794